K011738

JUN 2 0 2001

510(k) Summary

Introduction	According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.
1) Submitter name, address, contact	Roche Diagnostics Corporation 9115 Hague Rd. Indianapolis, IN 46250 (317) 845-2000 Contact Person: Mike Flis Date Prepared: June 4, 2001
2) Device name	Proprietary name: Accu-Chek Active System Classification name: Glucose dehydrogenase, glucose test system (21 C.F.R. § 862.1345)(75LFR)
3) Predicate device	We claim substantial equivalence to the current legally marketed Accu-Chek Simplicity System.
4) Device Description	Instrument Operating Principle -- photometry Reagent Test Principle -- glucose dehydrogenase
5) Intended use	The Accu-Chek Active system is designed to quantitatively measure the concentration of glucose in capillary whole blood. The device is indicated for professional use and over-the-counter sale.

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6) Similarities The Roche Diagnostics Accu-Chek Active System is substantially equivalent to the current legally marketed Accu-Chek Simplicity System. The proposed modification is relatively modest in scope. The following is a list of some of the claims and features unaffected by the proposed modification.

Feature/Claim	Detail
Intended use	The Accu-Chek Simplicity and Accu-Chek Active systems are designed to quantitatively measure the concentration of glucose in capillary whole blood. The test device is indicated for professional use and over-the-counter sale. This device is not suitable for testing neonate samples.
Test principle	Glucose dehydrogenase chemical reaction. The instrument measures the extent of color change (photometric) caused by the presence of glucose in the sample. The amount of color change is related to the glucose concentration in the blood sample.
Venous blood samples	Although the method comparison studies provide evidence that the device works acceptably with venous blood samples, the labeling is limited to use with capillary whole blood.
Monitor coding procedure	Code chip is provided with each carton of test strips.
Test strip storage conditions	Store at room temperature between +36° F(+2° C) and +86° F(+30° C).
Test strip operating conditions	Between +5° F(+10° C) and +104° F(+40° C).
Quality control testing frequency	Tests should be run with liquid quality control materials whenever a new vial of test strips is opened or an unusual blood test result is obtained.
Quality control acceptable range	The mean is strip lot specific and will be determined individually. The range of the controls is within ± 15 mg/dL or ± 15% compared to the determined mean.
Labeling instructions regarding expected results	The normal fasting adult blood glucose range for a non-diabetic is 70-105 mg/dL. One to two hours after meals, normal blood glucose levels should be less than 140 mg/dL. Doctors will determine the range that is appropriate for the patients.
Labeling instructions regarding response to unusual results	Run a quality control test, if the result is outside the acceptable QC recovery range contact Roche Diagnostics's Accu-Chek Customer Care center; if result is within the acceptable range, review proper testing procedure and repeat blood glucose test with a new test strip.
Acceptable sample types	Capillary whole blood samples
Reportable range	10-600 mg/dL
Hematocrit range	30 – 55%
Warnings and precautions	For *in vitro* diagnostic use only.

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7) Data demonstrating substantial equivalence	Performance testing on the modified Accu-Chek Active System demonstrated that the device meets the performance requirements for its intended use. A multi-center performance study was conducted to evaluate the accuracy and precision of the modified device. The clinical data demonstrates that the performance of the Accu-Chek Active correlates well with the laboratory plasma glucose reference test method. All predetermined acceptance criteria were satisfied. The data also demonstrates that the Accu-Chek Active is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 0 2001

Mr. Mike Flis
Regulatory Affairs Principal
Roche Diagnostics corporation
9115 Hague Road
Indianapolis, IN 46250

Re: 510(K) Number: K011738
Trade/Device Name: Accu-Chek Active Test System
Regulation Number: 862.1345
Regulatory Class: II
Product Code: NBW, LFR
Dated: June 4, 2001
Received: June 5, 2001

Dear Mr. Flis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K011738
Device Name: Accu-Chek Active Test System

Indications for Use:

The Accu-Chek Active system is designed to quantitatively measure the concentration of glucose in capillary whole blood. The device is indicated for professional use and over-the-counter sale.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Fred Lacy
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011738

Prescription Use _____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)